



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9127-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances— October through December 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from October through December 2020, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410) 786-7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	William Parham	(410) 786-4669
VII Medicare –Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX Medicare’s Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786-3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786-3365
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786-3365
All Other Information	Annette Brewer	(410) 786-6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance.

Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How to Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: February 22, 2021.

Trenesha Fultz-Mimms,

Federal Register Liaison,

Department of Health and Human Services.

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: February 13, 2020 (85 FR 8282), April 24, 2020 (85 FR 23030), August 12, 2020 (85 FR 48691), and November 4, 2020 (85 FR 70168). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (October through December 2020)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general

public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Update to Medicare Deductible, Coinsurance and Premium Rates for Calendar Year (CY) 2021, use (CMS-Pub. 100-01) Transmittal No. 10469.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

Please Note: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
10447	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10461	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10469	Update to Medicare Deductible, Coinsurance and Premium Rates for Calendar Year (CY) 2021
10493	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10507	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
Medicare Benefit Policy (CMS-Pub. 100-02)	
10437	Manual Updates Related to the Hospice Election Statement and the Implementation of the Election Statement Addendum Hospice Election Statement Hospice Election Statement Addendum Hospice Notice of Election Short-Term Inpatient Care
10438	Home Health Manual Update to Incorporate Allowed Practitioners into Home Health Policy
10451	Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2021

10463	<p>Billing for Home Infusion Therapy Services On or After January 1, 2021</p> <p>Home Infusion Therapy Services</p> <p>General Requirements for Payment of Home Infusion Therapy Services</p> <p>Home Infusion Therapy Services Benefit is Separate from DME Benefit</p> <p>Qualified Home Infusion Therapy Suppliers</p> <p>Patient Eligibility for Home Infusion Therapy</p> <p>Home Infusion Therapy Services for Homebound Patients Plan of Care Requirements</p> <p>Notification of Available Infusion Therapy Options</p> <p>Plan of Care Periodic Review and Provider Coordination</p> <p>Professional Services, Including Nursing Services, for Home Infusion</p> <p>Home Infusion Therapy Services Training and Education</p> <p>Remote Monitoring and Monitoring Services</p> <p>Home Infusion Therapy Drugs</p> <p>Determining Qualifying Home Infusion Drugs</p> <p>Payment for Home Infusion Therapy Services</p> <p>Home Infusion Drug Payment Categories</p> <p>Infusion Drug Administration Calendar Day and Unit of Single Payment</p> <p>Initial Visits and Subsequent Visits for Home Infusion Therapy Services</p> <p>Medical Review</p>
10490	Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2021
10541	January 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10547	<p>Billing for Home Infusion Therapy Services On or After January 1, 2021</p> <p>TOC</p> <p>Home Infusion Therapy Services</p> <p>General Requirements for Payment of Home Infusion Therapy Services</p> <p>Home Infusion Therapy Services Benefit is Separate from DME Benefit</p> <p>Qualified Home Infusion Therapy Suppliers</p> <p>Patient Eligibility for Home Infusion Therapy</p> <p>Home Infusion Therapy Services for Homebound Patients Plan of Care Requirements</p> <p>Notification of Available Infusion Therapy Options</p> <p>Plan of Care Periodic Review and Provider Coordination</p> <p>Professional Services, Including Nursing Services, for Home Infusion Therapy</p> <p>Home Infusion Therapy Services Training and Education</p> <p>Remote Monitoring and Monitoring Services</p> <p>Home Infusion Therapy Drugs</p> <p>Determining Qualifying Home Infusion Drugs</p> <p>Payment for Home Infusion Therapy Services</p> <p>Home Infusion Drug Payment Categories</p> <p>Infusion Drug Administration Calendar Day and Unit of Single Payment</p> <p>Initial Visits and Subsequent Visits for Home Infusion Therapy Services</p> <p>Medical Review</p>
Medicare National Coverage Determination (CMS-Pub. 100-03)	
10454	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy
Medicare Claims Processing (CMS-Pub. 100-04)	
10382	October 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.3
10385	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10386	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10388	Issued to a specific audience, not posted to Internet/Intranet due to

	Confidentiality of Instructions
10390	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10391	January 2021 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
10396	Ambulance Inflation Factor (AIF) for Calendar Year (CY) 2021 and Productivity Adjustment Ambulance Inflation Factor (AIF)
10397	New Waived Tests
10398	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10399	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10402	Change to the Payment of Allogeneic Stem Cell Acquisition Services
10403	Penalty for Delayed Request for Anticipated Payment (RAP) Submission -- Implementation
10407	Internet Only Manual Update, Pub. 100-04, Chapter 11 - This CR Rescinds and Fully Replaces CR 11807
10408	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2020 Update
10410	October Quarterly Update for 2020 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
10413	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10414	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10416	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10421	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10423	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10425	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10426	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10428	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10431	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10433	Quarterly Update to Home Health (HH) Grouper
10435	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10439	Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2021
10440	Instructions for Retrieving the 2021 Pricing and Healthcare Common Procedure Coding System (HCPCS) Data Files through CMS' Mainframe Telecommunications Systems
10441	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10443	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10444	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10445	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10448	Updates to Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM) Claims

	Patient Readmitted Within 30 Days After Discharge Total and Noncovered Charges
10453	Internet Only Manual Update, Pub. 100-04, Chapter 11 - This Change Request (CR) Rescinds and Fully Replaces CR 11807.
10454	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy
10456	Update to Vaccine Services Editing
10457	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10460	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10463	Billing for Home Infusion Therapy Services On or After January 1, 2021
10472	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
10473	Claim Status Category and Claim Status Codes Update
10476	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
10485	Internet Only Manual Update, Pub. 100-04, Chapter 11 - This CR Rescinds and Fully Replaces CR 11807.
10487	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10488	Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2021
10494	Shared System Support Hours for Application Programming Interfaces (APIs)
10496	April 2021 Update to the Fiscal Year (FY) 2021 Inpatient Prospective Payment System (IPPS)
10497	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10498	Update to the Federally Qualified Health Center (FQHC) Prospective Payment System (PPS) for Calendar Year (CY) 2021 - Recurring File Update
10502	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10503	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10504	2021 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
10505	Summary of Policies in the Calendar Year (CY) 2021 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, CT Modifier Reduction List, and Preventive Services List
10506	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10510	Instructions for Downloading the Medicare ZIP Code Files for April 2021
10511	Calendar Year (CY) 2021 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures
10512	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10513	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10514	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10516	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10521	New Medicare National Uniform Billing Committee (NUBC) Type of Bill (TOB), Condition Code and implementing Billing Codes for Opioid Treatment Programs Practitioner Claims submission – A/B MAC (B) Institutional Opioid Treatment Program (OTP) Services – A/B MAC (A)

	Special Opioid Treatment Program Billing Requirements for Hospitals, Critical Access Hospitals, and Free-Standing Opioid Treatment Program Facilities
10522	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10523	Calendar Year (CY) 2021 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10531	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10534	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10535	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 27.1, Effective April 1, 2021
10540	January 2021 Integrated Outpatient Code Editor (I/OCE) Specifications Version 22.0
10542	2021 Annual Update to the Therapy Code List
10543	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10546	January 2021 Update of the Ambulatory Surgical Center (ASC) Payment System
10547	Billing for Home Infusion Therapy Services On or After January 1, 2021 Home Infusion Therapy Services Policy Coverage Requirements Home Infusion Drugs: Healthcare Common Procedural Coding System (HCPCS) Drug Codes Billing and Payment Requirements Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages CWF and MCS Editing Requirements
Medicare Secondary Payer (CMS-Pub. 100-05)	
10401	Electronic Correspondence Referral System (ECRS) User Guide Updates ECRS Web User Guide, Software Version 6.4 ECRS Web Quick Reference Card, Version 2020/5
Medicare Financial Management (CMS-Pub. 100-06)	
10387	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
10394	Notice of New Interest Rate for Medicare Overpayments and Underpayments -1st Qtr Notification for FY 2021
10405	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10521	New Medicare National Uniform Billing Committee (NUBC) Type of Bill (TOB), Condition Code and Implementing Billing Codes for Opioid Treatment Programs Type of Bill
10527	Pub. 100-06, Chapter 4, Section 10 Revision (New Accounts Receivable (AR) Status Codes for Undeliverable Initial Demand Letters and Terminated/Out of Business Providers) Requirements for Collecting Part A and B Provider Non-MSP Overpayments
Medicare State Operations Manual (CMS-Pub. 100-07)	
	None
Medicare Program Integrity (CMS-Pub. 100-08)	
10383	Updates to Chapters 4, 5, 8, 15, and Exhibits of Publication (Pub.) 100-08
10439	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10400	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10404	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

10406	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10411	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10418	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10419	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10420	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10434	Update to Chapter 10 of Publication (Pub.) 100-08 - Enrollment Policies for Home Infusion Therapy (HIT) Suppliers
10436	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10442	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10450	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10467	Update to Chapter 10 of Publication (Pub.) 100-08 - Enrollment Policies for Home Infusion Therapy (HIT) Suppliers
10468	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10480	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10481	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10489	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10492	Clarifying The Use of As-Needed/PRN Orders for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
10509	Unified Program Integrity Contractor (UPIC) Coordination with Other Contractors Related to the Recovery Audit Contractor (RAC) Data Warehouse (RACDW) - Exclusion Clarification UPIC Coordination with Other Contractors Related to the RAC Data Warehouse
10524	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional Release of Chapter 10Enrolling to Receive Medicare Payment General Summary of Process to Enroll in Medicare General Overview of Medicare Enrollment Application Forms Suppliers That Enroll Via the Form CMS-855S Medicare Enrollment Forms: Information and Processing CMS-855 Series Enrollment Forms: Information and Processing Enrollment Form: Information and Processing Other Enrollment Forms: Information and Processing Additional Topics Pertaining to Medicare Enrollment Certified Providers/Suppliers Establishing Effective Dates Legal Business Name National Provider Identifier (NPI) Final Adverse Actions Owning and Managing Information Billing Agencies Contact Persons Medicare Payment Participation (Par) Agreements and the Acceptance of Assignment Opting-Out of Medicare Ordering/Certifying Suppliers

10536	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
10538	Clarifying The Use of As-Needed/PRN Orders for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Evidence of Medical Necessity
10539	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
10455	Updates to Pub. 100-09, Chapter 6 Beneficiary and Provider Communications Manual, Chapter 6, Provider Customer Service Program
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Medicare Prescription Drug Benefit (CMS-Pub. 100-18)	
	None
Demonstrations (CMS-Pub. 100-19)	
10392	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10415	Primary Care First (PCF) and Serious Illness Patient (SIP) Models: Part 3: IURs and Edits for Non-Sequential Claims
10465	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10466	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10479	Implementation of Nurse Practitioners Certifying Diabetic Shoe Orders Under the Primary Care First (PCF) Model
10482	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10483	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10484	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10517	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10518	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10526	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10533	Telehealth Expansion Benefit Enhancement under the Pennsylvania Rural Health Model (PARHM) – Implementation
10537	Primary Care First (PCF) and Serious Illness Patient (SIP) Models: Part 2: FFS Payments and Other Claims-Based Adjustments
One Time Notification (CMS-Pub. 100-20)	
10409	Utility to Reprocess Bypassed Common Working File (CWF) Informational Unsolicited Responses (IURs)
10412	Special Provisions for Radiology Additional Documentation Requests
10417	Update to the Fiscal Intermediary Shared System (FISS) Integrated Outpatient Code Editor (IOCE) Claim and Return Buffer Interface Changes
10422	Send Electronic Funds Transfer (EFT) Information from Provider Enrollment

	Chain and Ownership System (PECOS) to Multi-Carrier System (MCS) Phase 2
10424	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for April 2021
10429	Processing of Multiple Unsolicited Responses on the Same Home Health Claims
10430	Treatment Choices (ETC) Model Implementation: Home Dialysis Payment Adjustment (HDP) & Waiver of the Kidney Disease Education (KDE) Benefit
10432	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)—April 2021
10446	Viable Information Processing Systems (ViPS) Medicare Systems (VMS) Changes to Accommodate National Provider Identifier Associations
10449	Part A Opt Out Common Working File (CWF) Report
10452	Implementation of the Award for the Jurisdiction 6 Part A and Part B Medicare Administrative Contractor (J-6 A/B MAC)
10458	Direct Mailing Notification to Hospice Providers Regarding the Hospice Benefit Component, Value-Based Insurance Design (VBID) Model, for Participating Medicare Advantage Organizations (MAOs)
10462	Implementation of the Award for the Jurisdiction C Durable Medical Equipment Medicare Administrative Contractor (JC DME MAC)
10470	Implementation of Two (2) New NUBC Condition Codes. Condition Code “90”, “Service provided as Part of an Expanded Access Approval (EA)” and Condition Code “91”, “Service Provided as Part of an Emergency Use Authorization (EUA)”
10471	Provide Systematic Auto-Inactivation of SuperOp Events for Related Entity Action Records (EARs) in ViPS Medicare System (VMS) – Implementation of User CR 11397
10475	April 2021 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
10478	User CR: ViPS Medicare System (VMS) - Create a Beneficiary Record Submitted with Medicare Beneficiary Identifier (MBI) Waiver Claims
10486	Updates to Nursing and Allied Health Education Medicare Advantage Payment Policies
10491	Medicare Administrative Contractors (MACs) to Allow Medicare Diabetes Prevention Program (MDPP) Suppliers to Use the Same Centers for Disease Control (CDC) Organizational Codes
10495	ESRD Treatment Choices (ETC) Model Implementation: Home Dialysis Payment Adjustment (HDP) & Waiver of the Kidney Disease Education (KDE) Benefit
10499	COBOL Version 6.2 Upgrade - Phased Implementation for ViPS Medicare System (VMS) and the Common Working File (CWF)
10500	COBOL Version 6.2 Upgrade - Phased Implementation for Fiscal Intermediary Shared System (FISS) and Multi Carrier System (MCS)
10501	Shared Systems Report of Medicare Summary Notice (MSN) Counts by Type
10508	Update to the Fiscal Intermediary Shared System (FISS) Integrated Outpatient Code Editor (IOCE) Claim and Return Buffer Interface Changes
10515	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)—April 2021
10520	Updates to Nursing and Allied Health Education Medicare Advantage Payment Policies
10525	Implementation of the New Ambulatory Surgical Center (ASC) Payment Indicator “K5”
10528	Updating Calendar Year (CY) 2021 Medicare Diabetes Prevention Program (MDPP) Payment Rates
10529	Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) Codes 87811 and 87428

10530	Instructions to Medicare Administration Contractor (MAC) on COVID-19 Emergency Declaration Blanket Waivers for Medicare-Dependent, Small Rural Hospitals and Sole Community Hospitals
10545	ESRD Treatment Choices (ETC) Model Implementation: Home Dialysis Payment Adjustment (HDP) & Waiver of the Kidney Disease Education (KDE) Benefit
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
	None
State Payment of Medicare Premiums (CMS-Pub.100-24)	
	None
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
10459	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

Addendum II: Regulation Documents Published in the Federal Register (October through December 2020)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <http://www.gpoaccess.gov/fr/index.html>. The following website <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: <https://www.cms.gov/files/document/regs4q20qpu.pdf>

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (October through December 2020)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (October through December 2020)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers	NCD 110.24	10454	11/31/2020	08/17/2019

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October through December 2020) (Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (October through December 2020)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities (October through December 2020)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing

carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Hospital Damas, Inc. 2213 Ponce By Pass Ponce, PR 00717-1318	400022	09/29/2020	PR
Wyckoff Medical Center 374 Stockolm Street Brooklyn, NY 11237	330221	11/03/2020	NY
Ascension Sacred Heart Emerald Coast 7800 U.S. Highway 98 West Miramar Beach, FL 32550	1558391771	11/10/2020	FL
Lower Bucks Hospital 501 Bath Road Bristol, PA 19007	390070	11/24/2020	PA
Texas Health Presbyterian Hospital Plano 6200 West Parker Road Plano, TX, 75093	450771	12/15/2020	TX
Centerpoint Medical Center 19600 East 39th Street Independence, MO 64057	1942247044	12/15/2020	MO
Jamaica Hospital Medical Center 8900 Van Wyck Expressway Jamaica, NY 11418	330014	12/15/2020	NY
Providence St. Mary Medical Center 401 W. Poplar Street Walla Walla, WA 99362	500002	12/22/2020	WA
The following facilities have editorial changes (in bold).			
Our Lady of Lourdes Regional Medical Center 4801 Ambassador Caffery Parkway Lafayette, LA 70508	190102	05/03/2005	LA
FROM: Amisub of South Carolina, Inc TO: Piedmont Medical Center 222 S. Herlong Avenue Rock Hill, SC 29732	420002	06/14/2005	SC

Addendum VIII:

American College of Cardiology's National Cardiovascular Data Registry Sites (October through December 2020)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (October through December 2020)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X:

List of Special One-Time Notices Regarding National Coverage Provisions (October through December 2020)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at <http://www.cms.gov>. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (October through December 2020)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission

tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilities/NOPR/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (October through December 2020)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilities/VAD/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
The following facilities are new listings for this quarter.				
Norton Hospitals Inc 4965 US 42 Suite 2000 Louisville, KY 40222	180088	09/17/2020		KY
Other information: DNV-GL # 186245-2020-VAD				

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
The following facilities have editorial changes (in bold).				
Lovelace Medical Center 601 Dr. Martin Luther King Jr. Avenue NE Albuquerque, NM 87102 Other information: DNV-GL # 460807-2020-VAD	320009	10/09/2017	08/27/2020	NM
FROM: The Medical Center of Central Georgia TO: Medical Center Navicent Health 777 Hemlock Street Macon, GA 31201 Other information: DNV-GL # 492949-2020-VAD Previous Re-certification Dates: 2018-11-14; 2014-10-21; 2016-11-22	110107	11/08/2012	10/13/2020	GA
FROM: University Health Care System. TO: University Health Services, Inc d/b/a University Hospital 1350 Walton Way Augusta, GA 30901 Other information: DNV GL #: 564723-2020-VAD	110028	08/16/2017	08/28/2020	GA

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October through December 2020)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at

www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October through December 2020)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October through December 2020)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2021-05539 Filed: 3/16/2021 8:45 am; Publication Date: 3/17/2021]